



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/242,540 02/18/99 BIEDERMANN

E 64978

EXAMINER

HM12/0306

FITCH EVEN TABIN & FLANNERY
135 SOUTH LASALLE STREET
SUITE 900
CHICAGO IL 60603-4277

ART UNIT	PAPER NUMBER
----------	--------------

1624
DATE MAILED:

16
03/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/242,540

Applicant(s)
BIEDERMANN et al.

Examiner
Brenda Coleman

Group Art Unit
1624



☒ Responsive to communication(s) filed on Dec 11, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 42-67 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 42-67 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 15

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1624

DETAILED ACTION

Claims 42-67 are pending in the application.

This action is in response to applicants' amendment dated December 11, 2000. Claims 1-41 were canceled and claims 42-67 are newly added.

Response to Arguments

Applicant's arguments filed December 11, 2000 have been fully considered with the following effect:

1. The applicant's amendments are sufficient to overcome the improper Markush rejection of the last office action which is hereby **withdrawn**.
2. The applicant's amendments are sufficient to overcome the 35 USC § 112, second paragraph rejections labeled a), c)-e), g)-i), k)-ar) and au)-bo). However, with regards to the 35 U.S.C. § 112, second paragraph rejection labeled b), f), j), as) and at) of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

b) The applicants' stated that the rejections of the claims "have been obviated as these claims have been canceled and replaced with the claims provided herewith".

However, the definition of R¹ in claims 42 and 52-65 still contain a moiety which is a C₁ alkanoyloxy. Alkanoyl is an alkyl-C(=O)- moiety and hence must have at least 2 carbon atoms.

Newly added claims 42 and 52-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and

Art Unit: 1624

distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

- f) The applicants' stated that the rejections of the claims "have been obviated as these claims have been canceled and replaced with the claims provided herewith". However, the definition of R^9 in claims 42 and 52-65 still contain a moiety which is a C_1 acyl. Acyl is defined as an organic radical derived from an organic acid by the removal of the hydroxyl group, e.g., $R-C(=O)-$, and hence must have at least 2 carbon atoms.

Newly added claims 42 and 52-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

- j) The applicants' stated that the rejections of the claims "have been obviated as these claims have been canceled and replaced with the claims provided herewith". However, the list of substituents for the aryl residues and/or aromatic ring systems in claims 42 and 52-65 still contain a moiety which is a C_1 alkoxycarbonyl. Alkoxycarbonyl is an $alkyl-O-C(=O)-$ moiety and hence must have at least 2 carbon atoms.

Newly added claims 42 and 52-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and

Art Unit: 1624

distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

as) The applicants' stated that the rejections of the claims "have been obviated as these claims have been canceled and replaced with the claims provided herewith".

Claims 52-54 recites the limitation "reactive derivatives" in reference to formula II.

There is insufficient antecedent basis for this limitation in the claim. There is no indication within the claim as to what this embraces.

Newly added claims 52-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

at) The applicants' stated that the rejections of the claims "have been obviated as these claims have been canceled and replaced with the claims provided herewith".

However, the definition of L in claims 52-54 contain a moiety which is a suitable nucleofuge. It is not known what is meant by a suitable nucleofuge.

Newly added claims 52-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

Art Unit: 1624

3. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 101, rejection of the last office action which is hereby **withdrawn**.

4. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection of the last office action which is hereby **withdrawn**.

5. With regards to the 35 USC § 103, obviousness rejection of claims 1-8 and 14-40 over Goto et al., EP 330 026 (U.S. equivalent 5,169,8560), of the last office action, the applicants' arguments have been fully considered but are not found persuasive. The applicants' stated in the amendment "that one of ordinary skill in the art would have no motivation or reasonable expectation that compounds described in the '026 reference could be selected, modified and be used as anti-cancer agents as claimed herein". However, the motivation to make the compounds and pharmaceutical compositions is "the reference" in and of itself. The use of the compounds in the reference is irrelevant with respect to the compounds and composition claims.

Claims 42-46, 52-54, 56-58 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goto et al., EP 330 026. For reasons of record and stated above.

6. With regards to the obviousness-type double patenting rejection of claims 1-8 and 14-40 over claims 41-47 and 54-59 of copending Application NO. 09/216,075 of the last office action, the applicants' arguments have been fully considered but are not found persuasive. The applicants' stated in the "amendments to be filed in serial number 09/216,075 obviate and will obviate further double patenting rejections". However, the applicants' have not indicated exactly

Art Unit: 1624

how the claims of serial number 09/216,075 are amended and our records show at this time that no amendment has been filed in serial number 09/216,075.

Claims 42-46 and 52-67 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 41-47 and 54-79 (upon further review of the claims) of copending Application No. 09/216,075. For reasons of record and stated above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. With regards to the obviousness-type double patenting rejection of claims 1-40 over claims 33-35 of copending Application NO. 09/216,482 of the last office action, there were no arguments presented with respect to this rejection.

Claims 42-67 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20-37 (upon further review of the claims) of copending Application No. 09/216,482. For reasons of record and stated above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

In view of the amendment dated December 11 2000, the following new grounds of rejection apply:

Art Unit: 1624

Information Disclosure Statement

8. One of the journal articles, i.e. R. Fischer, "Allgemeine Pathologie und Pathologische Anatomie" is missing the publication date which is required for citation upon allowance of the application. The applicants' are reminded that the publication date is needed to complete the record.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 42, 46 and 52-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 42 and 52-65 are vague and indefinite in that it is not known what is meant by the phrase " R^1 and R^2 , **in the case** they are adjacent".
- b) Claim 46 recites the limitation "diphenylphosphinoyl" in the definition of G. There is insufficient antecedent basis for this limitation in the claim.
- c) Claims 52-54 are vague and indefinite in that there are two different definitions for the variable R^4 within the claim.
- d) Claims 52-54 are vague and indefinite in that there are several different definitions for the variable L within the claim.

Art Unit: 1624

- e) Claims 64-67 indicate "comprising administering to the human or animal body an effective amount" which is unclear as to whether this is indicative of a subject in need thereof.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 42-46, 52-54, 56-58 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Goto et al., U.S. Patent Number 5,169,856. Goto teaches the compounds of the instant invention where A is ethenylene; R₄ is hydrogen; D is ethylene; E is piperidin-4-yl; and G is benzyl. The species excluded by proviso is not sufficient to overcome this rejection since the species excluded is the hydrochloride salt of the compound. The compound taught by Goto is "the compound" and any salts thereof.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Monday thru Friday from 9:00 AM to 5:30 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Application/Control Number: 09/242,540

Page 9

Art Unit: 1624

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, reading "Brenda Coleman". The signature is fluid and cursive, with a long horizontal stroke extending from the end of the name.

Brenda Coleman
March 5, 2001